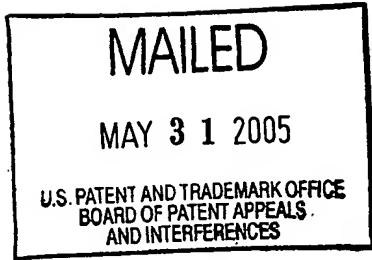


The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES



Ex parte LOUIS I. NDIFE, BOOKER T. LUCAS III,
and STEPHENE L. HOHMAN

Appeal No. 2005-1290
Application No. 10/603,464

ON BRIEF

Before GARRIS, PAK, and WALTZ, Administrative Patent Judges.
PAK, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 through 11 and 14, which are all the claims pending in the above-identified application.

APPEALED SUBJECT MATTER

The subject matter on appeal is directed to a single serving infant formula tablet which can be dissolved rapidly in water. See the specification, page 1, lines 4-6. According to the appellants (specification, page 3, lines 3-5), this dissolution characteristic

is due to "the force used to compress the tablet". The tablet is formed under a particular pressure to prevent a film of fat from forming on the exterior tablet surface. Details of the appealed subject matter are recited in representative claims 1 and 14 which are reproduced below:

1. An infant formula in tablet form comprising:

- a) a source of protein, present in the amount of 10 to 20 w/w%;
- b) a source of carbohydrate, present in the amount of 40 to 70 w/w%; and
- c) a source of fat present in the amount of at least 20 w/w%;

wherein the infant formula is a tablet formed under a pressure selected from within a range of from about 400 psi to about 1500 psi, and wherein the pressure is selected so that a film of fat does not form on the exterior tablet surface, and wherein the resulting infant formula tablet dissolves within 60 seconds in accordance with a manual dissolution test.

14. An infant formula in tablet form comprising, based on a 100 kcal basis:

- a) about 8 to about 16 grams of a source of carbohydrate,
- b) about 3 to about 6 grams of a source of fat, and
- c) about 1.8 to about 3.3 grams of a source of protein,

wherein the infant formula is a tablet formed under a pressure selected from within a range of from about 400 psi to about 1500 psi, and wherein the pressure is selected so that a film of fat does not form on the exterior tablet surface, and wherein the resulting infant formula tablet dissolves within 60 seconds in accordance with a mechanical dissolution test.

The claimed terminologies "infant", "manual dissolution test" and "mechanical dissolution test" are defined at pages 3 and 4 of the specification.

PRIOR ART REFERENCES

The prior art references relied upon by the examiner are¹:

Lamb	3,608,064	Sep. 21, 1971
Jang et al. (Jang)	4,894,236	Jan. 16, 1990
Brochner	894,001	Apr. 18, 1962
(Published British Patent Application)		
Ozalvo et al (Ozalvo)	WO 03/077664 A1	Sep. 25, 2003
(Published International Patent Application)		

The Merck Index, 10th ed., page MISC-87 (1983) (hereinafter referred to as "Merck").

OnlineConversion.com (Pressure Conversion)(unknown publication date). (hereinafter referred to as "Online")

REJECTIONS

Claims 1 through 11 and 14 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combined disclosures of Brochner and Ozalvo.

OPINION

We have carefully reviewed the claims, specification and applied prior art, including all of the arguments advanced by both the examiner and the appellants in support of their respective positions. This review has led us to conclude that the examiner's Section 103 rejection is not well founded. Accordingly, we will not sustain the examiner's Section 103

¹ The examiner has not included Merck, Online, Lamb and Jang in the statement of rejection. Normally, we do not consider the references not included in the statement of the rejection. *In re Hoch*, 428 F.2d 1341, 1342 n.3, 166 USPQ 406, 407 n.3 (CCPA 1970) ("Where a reference is relied on to support a rejection, whether or not in 'a minor capacity,' there would appear to be no excuse for not positively including the reference in the statement of the rejection."). However, even were we to consider them, our determination below would not be altered for the reasons set forth *infra*.

rejection for essentially those reasons set forth in the Brief. We add the following primarily for emphasis and completeness.

As our reviewing court stated in *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992):

[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.

This initial burden is not met unless the examiner supplies a sufficient factual basis to support her rejection. *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968)(The examiner may not resort to speculation to supply deficiencies in its factual basis.).

Here, we find that Ozalvo teaches Enfamil premature powder produced by Mead Johnson which were formed into tablets by compressing under a weight of 0.25 tons in a press machine. See page 11. We find that Ozalvo then goes on to imply that this tabulating method may not be applicable to different infant formulas. *Id.* Thus, on this record, notwithstanding the examiner's position to the contrary, we determine that the examiner has not demonstrated that the tabulating method (compression weight) for Enfamil premature powder is desirable for the composition of the type described in Brochner. See *In re Kotzab*, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000)(“to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant”). In this regard, we note

that the examiner has not identified any teaching or suggestion of desirability of tabulating Brochner's composition containing "10-29% of butter fat, 7-15% of milk proteins, 15-65% of milk carbohydrates and minor amounts of inorganic milk constituents and water" in the same manner as Enfamil premature powder.

Even if the tabulating method (the same compression weight) used for forming Enfamil tablets were employed in tabulating the composition described in Brochner as proposed by the examiner, we determine that the examiner has not demonstrated that the resulting tablets would necessarily have the same characteristics as those claimed, i.e., tablets having a specific dissolution rate and no fat film. As properly argued by the appellants (Brief, page 4), for example, to avoid a film of fat on the surface of the tablets, the claims require a further selection of an appropriate pressure from the recited pressure range. The examiner has not demonstrated that the prior art references relied upon recognize, *inter alia*, a particular pressure as a solution to avoiding the problem associated with the composition of the type described in Brochner (i.e., forming a film of fat on the surface of the tablets). Nor has the examiner demonstrated that the employment of the tabulating method taught in Ozalvo would necessarily result in tablets having the claimed attributes. Thus, on this record, the examiner has not supplied sufficient facts to demonstrate that the prior art references would have suggested the claimed tablets or that the tablets suggested would necessarily or inherently have the claimed features. *In re Spormann*, 363 F.2d 444, 447, 150 USPQ 449, 452 (CCPA 1966) ("[T]he inherency of an

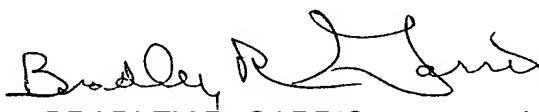
advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.”).

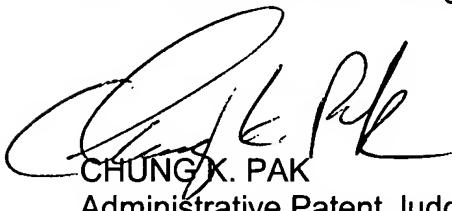
Under the circumstances recounted above, we determine that the examiner has not established a *prima facie* case of obviousness regarding the claimed subject matter. Accordingly, we reverse the examiner’s decision rejecting the claims on appeal under Section 103.

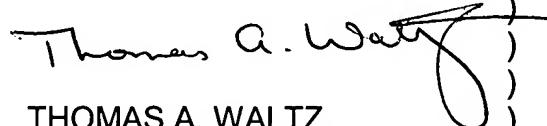
CONCLUSION

In view of the foregoing, we reverse the examiner's Section 103 rejection.

REVERSED


BRADLEY R. GARRIS)
Administrative Patent Judge)


CHUNG K. PAK) BOARD OF PATENT
Administrative Patent Judge) APPEALS
) AND
) INTERFERENCES


THOMAS A. WALTZ)
Administrative Patent Judge)

Appeal No. 2005-1290
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